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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,144	07/12/2007	George Tzertzinis	NEB-240-PUS	5689

28986 7590 07/18/2008  
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IPSWICH, MA 01938-2723

EXAMINER
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GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

MAIL DATE	DELIVERY MODE
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07/18/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,144	<b>Applicant(s)</b> TZERTZINIS ET AL.	
	<b>Examiner</b> TERRA C. GIBBS	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 1-18 are pending in the instant application.

Claims 1-18 are subject to restriction as detailed below:

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 10, drawn to composition comprising a plurality of dsRNA fragments having overlapping sequences, wherein the composition is formed by enzymatic digestion of one or more large dsRNAs and wherein the composition is capable of specifically silencing expression of a target gene in COS cells, wherein the targeted gene encodes Erk1, classifiable in class 536, subclass 24.5, for example.
- II. Claim 10, drawn to composition comprising a plurality of dsRNA fragments having overlapping sequences, wherein the composition is formed by enzymatic digestion of one or more large dsRNAs and wherein the composition is capable of specifically silencing expression of a target gene in COS cells, wherein the targeted gene encodes Erk2, classifiable in class 536, subclass 24.5, for example.
- III. Claim 15, drawn to a method of preparing a composition comprising a plurality of dsRNA fragments having overlapping sequences, wherein the composition is formed by enzymatic digestion of one or more large dsRNAs and wherein the composition is capable of specifically silencing

expression of a target gene in COS cells, comprising transcribing at least one RNA molecule having a sequence identity with a portion of a target gene, to form a large dsRNA; cleaving the large dsRNA by means of RNase III or mutants thereof; determining whether the large dsRNA can silence gene expression of the target gene in COS cells, and obtaining the composition comprising a plurality of dsRNA fragments having overlapping sequences, wherein the composition is formed by enzymatic digestion of one or more large dsRNAs and wherein the composition is capable of specifically silencing expression of a target gene in COS cells, classifiable in class 435, subclass 6, for example.

- IV. Claims 16-18, drawn to a method of silencing gene expression comprising cleaving with an enzyme, a dsRNA having sequence identity with a target gene, wherein the enzyme is RNase III or a mutant thereof and the cleavage product is a set of overlapping fragments of dsRNA; transfecting cells with the cleavage product, and obtaining silencing of expression of the target gene, classifiable in class, classifiable in class 514, subclass 44, for example.

Claims 1-9 and 11-14 links the invention of Groups I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-9 and 11-14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be

entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other, because of the following reasons:

Groups I and II are related to Group III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compositions comprising a plurality of dsRNA fragments having overlapping sequences, wherein the composition is formed by enzymatic digestion of one or more large dsRNAs and wherein the composition is capable of specifically silencing expression of a target gene in COS cells of Groups I and II can be used in materially different process such as a hybridization probe in a method of identifying target gene expression *in situ*, which is a materially different process than the method of silencing gene expression comprising cleaving with an enzyme, a dsRNA having sequence identity with a target gene, wherein the enzyme is RNase III or a mutant thereof and the cleavage product is a set

of overlapping fragments of dsRNA of Group III. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

Group II is drawn to a method of preparing a composition comprising a plurality of dsRNA fragments having overlapping sequences, wherein the composition is formed by enzymatic digestion of one or more large dsRNAs and wherein the composition is capable of specifically silencing expression of a target gene in COS cells, comprising transcribing at least one RNA molecule having a sequence identity with a portion of a target gene, to form a large dsRNA; cleaving the large dsRNA by means of RNase III or mutants thereof; determining whether the large dsRNA can silence gene expression of the target gene in COS cells, and obtaining the composition comprising a plurality of dsRNA fragments having overlapping sequences, wherein the composition is formed by enzymatic digestion of one or more large dsRNAs and wherein the composition is capable of specifically silencing expression of a target gene in COS cells and is considered to be distinct from the method of silencing gene expression comprising cleaving with an enzyme, a dsRNA having sequence identity with a target gene, wherein the enzyme is RNase III or a mutant thereof and the cleavage product is a set of overlapping fragments of dsRNA; transfecting cells with the cleavage product, and obtaining silencing of expression of the target gene of Group III. The inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive;

the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Group II is distinct from the method of Group III since the method of Group II recites distinct method steps and distinct objectives, apart from the method steps and objectives recited in Group III. Furthermore, Group II is distinct from Group III since the invention of Group II does not overlap in scope with that of Group III since each Group recites materially distinct methods which differ in criteria for success. Because these Groups utilize unique and different method steps, the inventions are also therefore not obvious variants, and have a materially different design. Furthermore, because these Groups utilize unique and different method steps, the prior art applicable to one Group would not likely be applicable to another Group and the inventions in each Group are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. Accordingly, restriction between these Groups is considered proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Also, because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions require a different field of search (see MPEP 808.02), restriction for examination purposes as indicated is proper.

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Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise



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include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

July 17, 2008

/Terra Cotta Gibbs/

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/589,144	TZERTZINIS ET AL.	
	Examiner	Art Unit	
	TERRA C. GIBBS	1635	